NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC. et al., Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) Civil Action No. 10-6241 (SRC) (MAS) (consolidated with 07-4417 for all purposes) **OPINION & ORDER**
HOFFMANN-LA ROCHE INC. et al., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 07-4516 (SRC) (MAS) Civil Action No. 08-3607 (SRC) (MAS) Civil Action No. 08-4055 (SRC) (MAS) Civil Action No. 10-5623 (SRC) (MAS) (consolidated with 07-4516 for all purposes)
HOFFMANN-LA ROCHE INC. et al., Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) Civil Action No. 10-6206 (SRC) (MAS) (consolidated with 07-4539 for all purposes)

HOFFMANN-LA ROCHE INC. et al., Plaintiffs, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE, ORCHID PHARMACEUTICALS INC., and ORGENUS PHARMA INC., Defendants.	Civil Action No. 07-4582 (SRC) (MAS) Civil Action No. 08-4051 (SRC) (MAS) Civil Action No. 10-4050 (SRC) (MAS) (consolidated with 07-4582 for all purposes)
HOFFMANN-LA ROCHE INC. et al., Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., GENPHARM ULC and GENPHARM, L.P., Defendants.	Civil Action No. 07-4661 (SRC) (MAS) Civil Action No. 08-4052 (SRC) (MAS) Civil Action No. 11-0579 (SRC) (MAS) (consolidated with 07-4661 for all purposes)

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for reconsideration, pursuant to Federal Rule of Civil Procedure 59(e), by Plaintiffs Hoffman-La Roche Inc. and Genentech, Inc. (collectively, "Roche"). For the reasons stated below, the motion will be denied.

Roche moves for reconsideration of certain aspects of this Court's Opinion entered May 7, 2012. Roche offers this summary of its arguments:

The Court's May 7, 2012 summary judgment opinion at page 40 overlooks

> evidence in the record of material factual disputes raised by Roche in its opposition to Defendants' summary judgment motion against its '634 patent -- namely, that the superior clinical results were unexpected and resulted from unexpected pharmacokinetic properties of Roche's drug ibandronate that Roche discovered at the previously untested 150 mg oral dose claimed in its patents.
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> Roche substantively pointed out expert witness testimony in support of its argument in its L. Civ. R. 56.1 statement of material facts in dispute, (*i.e.*, Counter-Statement of Fact (D.I. 432-2, C.A. No. 07-4417), "CSOF"). Roche respectfully seeks reconsideration of the Court's waiver holdings concerning (i) Roche's unexpected results argument (5/7/12 Op. 40) and (ii) the Court's holding that Roche's "non-linear bioavailability" contentions were first raised at oral argument and, therefore, waived. *Id.*

(Pl.'s Br. 2.) It is worth reading this carefully. Note that Roche does not contend that it made the relevant points in its summary judgment brief.[1] Rather, Roche asserts that this Court erred in its decisions on waiver because Roche had pointed out certain evidence in its L. Civ. R. 56.1 statement of facts. The legal question is thus: if a party cites evidence in its L. Civ. R. 56.1 statement which could, on review of the record, be viewed as raising a material factual dispute, is that alone sufficient to raise a factual dispute that precludes the entry of judgment as a matter of law for the movant? Is it improper to find waiver of a point that was not made in a brief, but is an inference a party feels the Court should have made from the L. Civ. R. 56.1 statements?

The starting point for any inquiry into the federal law of summary judgment is Federal Rule of Civil Procedure 56. Certainly this provides the foundation for considering Roche's argument that a point made in its L. Civ. R. 56.1 statement satisfies the procedural requirements

[1] Roche contends that it argued for reconsideration of the waiver holdings on pages 33-35 of its brief filed on May 25, 2012. It is interesting to note that, in that brief, Roche contended that it had in fact raised these arguments in its summary judgment opposition brief. (Docket Entry No. 496 at 33,34.) In the current brief, it has dropped that approach, relying instead on only its L. Civ. R. 56.1 statement. Yes, one heading in the brief in support of the instant motion contends that Roche had "briefed" the issue, but the following section fails to address or support that point. (Pls.' Br. 5.)

stated in Rule 56(c). The Federal Circuit has stated: "we have generally deferred to regional circuit law when the issue involves an interpretation of the Federal Rules of Civil Procedure." Manildra Milling Corp. v. Ogilvie Mills, 76 F.3d 1178, 1181-1182 (Fed. Cir. 1996). Thus, this Court looks to Third Circuit law in considering the procedural requirements of Rule 56(c).

In making its original decision, and again, now, this Court has relied on Third Circuit precedent which requires arguments to be actually made in an opening brief to be properly before the Court. For example:

> For the same reasons, we cannot construe Hoffecker's opening brief's statement that "[t]he procedure used by the government to suspend the statute of limitations pursuant to 18 U.S.C. § 3292 to permit it to obtain evidence in a foreign country did not satisfy the statute[,]" Appellant's Br. at 27, as raising the issue of whether the Government's application was improper on the basis that the Government filed it after the statute of limitations already had expired for Counts Two and Three. Although this sentence mentions section 3292, it does not construct any argument about the limitation period already having expired.
>
> Inasmuch as Hoffecker did not raise in his opening brief the issue of whether the section 3292 suspension application was improper because the Government filed it after the statute of limitations had expired on Counts Two and Three, he has waived the issue. Moreover, he cannot seek to raise the argument in a Rule 28(j) letter when he has not raised it in his opening brief.

United States v. Hoffecker, 530 F.3d 137, 163 (3d Cir. 2008). In the instant case, Roche does not point to any language in its summary judgment brief that might be considered even a glancing reference to the arguments it says this Court should have considered. Under Hoffecker, Roche has waived the arguments.

Roche implicitly relies on the proposition that a party opposing a motion for summary judgment has adequately raised an issue of material fact if it points to evidence in the L. Civ. R. 56.1 statement which, when considered with the opposing party's evidence, could demonstrate a

factual dispute. Roche offers no legal authority to support this principle, and this Court understands that to mean that Plaintiffs know of none. If Roche were correct about this implicit principle, it would mean that the Court bears the obligation of combing through all the evidence cited in the 56.1 statements and of sorting it to ascertain which factual issues are disputed. The Third Circuit does not impose this obligation on Courts. Parties must identify disputed issues in their briefs.

Roche attempts to find support for its position in Judge Newman's dissenting opinion in Hoffmann-La Roche Inc. v. Apotex Inc., 2012 U.S. App. LEXIS 21051, *21 (Fed. Cir. Oct. 11, 2012). Judge Newman disagreed with the majority's decision that this Court properly declined to consider Roche's bioavailability evidence presented at the preliminary injunction hearing. Id.

At the outset, this is a puzzling argument. Roche argues that the decision of the U.S. Court of Appeals for the Federal Circuit, now final, was wrong, and that the dissent was right. On what legal basis could this Court credit such an argument?

Furthermore, Roche overlooks the argument that Judge Newman made. Judge Newman did not contend that the majority was wrong on the factual foundation for its decision. Rather, Judge Newman argued that the majority's decision conflicted with the Federal's Circuit's holding in Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.), 676 F.3d 1063, 1075 (Fed. Cir. 2012): "a fact finder [must] consider all evidence relating to obviousness before finding a patent invalid on those grounds." Based on this principle, Judge Newman argued that this Court should have considered the evidence presented at the preliminary injunction hearing. The majority apparently disagreed with her application of this principle, writing:

> It appears that the secondary considerations evidence that Roche points to on appeal was not submitted or mentioned as part of its motion for a preliminary injunction. Instead, Roche attempted, in a single line near the end of its reply brief, to "incorporate by reference" its entire forty-page brief relating to a separate motion, J.A. 21958, a brief that, among numerous arguments, contained a few conclusory sentences with citations to portions of Roche's evidence of unexpected results. J.A. 24834-36. "District judges are not archaeologists," and it was not the court's burden to "excavate masses of papers in search of revealing tidbits" to help Roche satisfy its burden to obtain a preliminary injunction.

Hoffman, 2012 U.S. App. LEXIS 21051 at *13 (citation omitted).

This Court could not have said it better.[2] Plaintiffs here argue that this Court should have excavated their L. Civ. R. 56.1 statement in search of what Roche now says was important – though not important enough at the time, evidently, to have been argued in the summary judgment brief. Neither the Federal Circuit nor the Third Circuit impose such an obligation on this Court.

Even if this Court had considered the arguments and evidence that Plaintiffs now say was overlooked, Plaintiffs still have failed to persuade this Court that the conclusion of obviousness was in error. The Court considers all the evidence relating to obviousness and arrives at its conclusion as a matter of law. Roche contends that this Court overlooked evidence that the 150mg monthly dose showed greater bioavailability than might have been expected, and that this constitutes an unexpected result weighing against a conclusion of obviousness. This Court is not persuaded that, even if credited, this evidence weighs against the obviousness conclusion. As was made clear in the summary judgment Opinion, the evidence showed that monthly treatment

[2] Similarly, the Third Circuit has stated: "Judges are not like pigs, hunting for truffles buried in the record." Doeblers' Pa. Hybrids, Inc. v. Doebler, 442 F.3d 812, 820 (3d Cir. 2006) (quoting United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991)).

of osteoporosis with oral ibandronate was in the prior art. The question before the Court was whether the use of a 150mg dose was obvious, pursuant to 35 U.S.C. § 103. This Court concluded:

> The differences between the subject matter which the applicants sought to patent in claims 1-8 of the '634 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. The differences appear quite small and amenable to being bridged by the application of common sense and ordinary skill.

(Opinion of May 7, 2012 at 44.) This quote contains the crux of the Court's reasoning.

Evidence that the 150mg dosage was associated with greater bioavailability than would have been expected does not impact the conclusion that the differences between the claimed invention and the prior art appear quite small. As Defendants point out, evidence that the 150mg dosage was absorbed better by the body simply has no relevance to the core finding that the difference between the 150mg dose and the prior art was small. Plaintiffs have pointed to nothing which persuades this Court that this determination was in error.

Plaintiffs, in their reply brief, contend that the question is "whether 2.5 mg daily oral dosing produced the maximum attainable clinical benefit" and whether it was surprising to get better results with a monthly dose than with the daily dose. (Pls.' Reply Br. 4.) This Court does not see how these issues impact the § 103 inquiry in this case. As this Court stated:

> The only remaining question is whether these two options were predictable solutions. The law does not require absolute predictability; "[f]or obviousness under § 103, all that is required is a reasonable expectation of success." In re O'Farrell, 853 F.2d 894, 904 (Fed. Cir. 1988).

(Opinion of May 7, 2012 at 3.) All that is required is a reasonable expectation of success. Evidence that the success was even greater than might have been expected does not affect the

conclusion that there was a reasonable expectation of success.

The motion to alter judgment pursuant to Rule 59(e) will be denied.

For these reasons,

IT IS on this 25th day of January, 2013

ORDERED that Plaintiffs' motion for reconsideration (Docket Entry No. 543) is **DENIED**.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.